

REMARKS

Applicants have carefully reviewed the Office Action mailed December 29, 2006, prior to preparing this response. Currently claims 1-3, 5 and 7-52 are pending in the application, wherein claims 1 and 2 have been withdrawn from consideration consequent an Examiner-induced requirement for restriction. Applicants note that, although not indicated on the Summary page of the Office Action, claim 18 indeed is pending in the application. Claims 1-2 have been cancelled with this paper. Favorable consideration of the following remarks is respectfully requested.

Amendments

The specification has been amended with this paper. Support for the amendments to the specification may be found, for example, in originally filed claims 3-6. Such amendment to the specification is permitted under M.P.E.P. §608.01(I). No new matter has been added.

Claim 5 has been amended into independent form including the limitations of claim 3. Claims 22 and 29 have been amended to provide consistency with the limitations of claim 3. Namely, the term --member-- has been amended to state "element". Claims 51 and 52 have been amended to distinctly indicate referents to the first polymer.

Applicants respectfully request entry of these amendments, asserting amendments complying with requirements as to form may be permitted after final action in accordance with 37 CFR §1.116(b). Additionally, Applicants respectfully assert an amendment that will place the application either in condition for allowance or in better form for appeal may be entered after Final rejection. See M.P.E.P. §714.12. Applicants request the proposed amendments be entered, asserting the amendments do not raise the issue of new matter or present new issues requiring further consideration or search. Applicants believe the amendments place the claims in condition for allowance, or otherwise place the claims in better form for subsequent appeal.

Rejections

Claims 3, 5-17, 19-42 and 51-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al., U.S. Patent No. 6,024,722, in view of Huntjens, U.S. Patent No. 3,388,095. Applicants respectfully traverse this rejection. It is noted that claim 6 was cancelled from the application in a previous amendment, thus is not currently pending in the application.

In formulating the rejection of claim 3, it was apparently asserted that Rau discloses a polymer that can “contain a substantial number of polyvalent aromatic groups such as polyphenylene.” See Rau, at column 9, lines 64-66. The Examiner then suggests “Huntjens disclose a polymer with phenylene units comprising 1,4 polyphenylene.” See Office Action, December 29, 2006, page 3. The Office Action goes on to state that it “would have been obvious for one of ordinary skill in the art at the time Applicant’s invention was made to have provided for a polymer comprising substituted 1,4 polyphenylene in Rau et al in order to obtain articles having unique physical properties over a broad temperature range as taught in Huntjens.” See Office Action, December 29, 2006, page 3. Applicants respectfully disagree with this assessment, asserting there is no motivation to make the proposed modification as suggested in the rejection.

Rau seems to teach a shaft which may include a layer formed of a polyimide/liquid crystal polymer blend. See Rau, at column 9, lines 55-62. Rau goes on to state liquid crystal polymers “are rigid, rod-like macromolecules which typically contain a substantial number of polyvalent aromatic groups such as phenylene.” Rau, column 9, lines 63-66. Thus, it is a class of liquid crystal polymers which is disclosed regarding the identified portion of Rau.

Huntjens seems to teach a stabilized poly(2,6-dimethyl-1,4-phenylene)ether composition. See Huntjens, at column 1, lines 19-20. Huntjens seems to be concerned with the instability of poly(2,6-dimethyl-1,4-phenylene)ether compositions, stating “the polymer has been subject to embrittlement and discoloration when exposed to elevated temperatures in the presence of oxygen.” Huntjens, at column 1, lines 27-31. Huntjens discloses adding a minor portion of a 2-mercaptobenzimidazole to a composition containing poly(2,6-dimethyl-1,4-phenylene) to provide stability of the composition. See Huntjens, at column 1, lines 62-67. Huntjens states that poly(2,6-dimethyl-1,4-

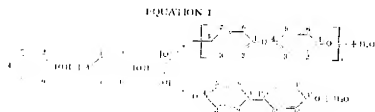
phenylene)ether is "one of a number of polyphenylene ethers disclosed and claimed in co-pending U.S. Patents Nos. 3,306,874 and 3,306,875." See Huntjens, at column 1, lines 21-24. Upon examination of the contents of these documents, Applicants respectfully note that these patents are directed to the oxidation of phenols, as evidenced in their respective titles. More precisely, Patent No. 3,306,874 states that:

The overall oxidation reaction to which my invention is directed is a reaction involving the hydrogen atom of the phenolic group of the phenol molecule, a hydrogen, chlorine, bromine, or iodine substituent in the para (4-) position of the phenol molecule and oxygen with the formation of water and polyarylene ethers (more specifically polyphenylene ethers) and/or diphenoquinones according to the following schematic diagram:



Similarly, Patent No. 3,306,875 states:

The overall oxidation reaction to which my invention is directed is a reaction involving the hydrogen atom of the phenolic group of the phenol molecule, a hydrogen, chlorine, bromine, or iodine substituent in the ortho (2-) or para (4-) position of the phenol molecule and oxygen with the formation of water according to the following schematic diagram using the para position for purposes of illustration:



From the teachings of U.S. Patent Nos. 3,306,874 and 3,306,875, it seems apparent that the composition disclosed in Huntjen, namely that of stabilized poly(2,6-dimethyl-1,4-phenylene)ether, is an ether having a carbon-oxygen-carbon bond, and does not possess the molecular structure of a liquid crystal polymer of the type disclosed in

Rau. It follows that one of ordinary skill in the art would not be inclined to substitute the stabilized polymeric composition disclosed in Huntjen (an ether), which does not possess the molecular structure of a liquid crystal polymer and thus is not considered a liquid crystal polymer, for a liquid crystal polymer disclosed in Rau. One of skill in the art would understand that the ether compound taught in Huntjen does not have similar physical characteristics sought by the inclusion of a liquid crystal polymer. Therefore, there simply is no motivation to make such a modification. One of ordinary skill in the art would not be inclined to look to teachings regarding the stabilization of a poly(2,6-dimethyl-1,4-phenylene)ether composition in an attempt to find a substitution for a liquid crystal polymer component of a device.

It follows that in reviewing the teachings of Huntjens, it is apparent that Huntjens is not in the field of the Applicants' endeavor, nor is its teachings reasonably pertinent to the particular problem with which the present invention is concerned. Namely, Huntjens is specifically concerned with the stabilization of a poly(2,6-dimethyl-1,4-phenylene)ether composition. Dissimilarly, the present application is primarily concerned with achieving the requirements of high levels of pushability, torqueability, and/or flexibility of medical devices. See Specification, page 1, lines 9-17. This is specifically reflected by claim 3, which is directed to a "medical device."

Applicants assert the Examiner has impermissibly collected various prior art documents in formulating the rejection without considering the inventive contributions attributed to the present application. In assessing the contributions of Huntjens, it appears as though the Examiner has simply found a reference which discloses a composition including 1,4 phenylene monomers, while disregarding the specific application or taking into account the absence of motivation to make the proposed modification.

An essential inquiry in attempting to establish a *prima facie* case of obviousness is "to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." M.P.E.P. §2143.01, quoting *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). Applicants assert that the prior art provides no motivation to make the proposed modification. One of skill

in the art, informed of the teachings of Rau and Huntjens, would not be inclined to arrive at that which is currently claimed, namely a medical device comprising an elongate flexible element made from a first polymer which is a substituted poly(1,4-phenylene).

At least because there is no motivation or suggestion to make the proposed modification, a *prima facie* case of obviousness has not been established. For at least this reason, claim 3, as well as claims 7-42 which depend from claim 3 and include significant additional limitations, is believed presently in condition for allowance and withdrawal of the rejection is respectfully requested.

Claim 5, which has been amended into independent form, is directed to a medical device comprising an elongate flexible element made from a first polymer which is a substituted poly(1,4-phenylene) including a plurality of benzoyl substituted 1,4-phenylene units. As noted in the Office Action, Rau fails to disclose a polymer comprising benzoyl substituted 1,4 phenylene units. See Office Action, December 29, 2006, page 3. Applicants respectfully disagree with the statement in the Office Action that “[i]t would have been obvious...to have selected benzoyl substituted 1,4 phenylene units, as benzoyl substituted 1,4 phenylene units are among the known phenylene units.” Office Action, December 29, 2006, pages 3-4. This statement is purely conclusory, and the Examiner has provided no documentary evidence in support of this assertion in accordance with M.P.E.P. §2144.03. Applicants note that the substituted portion of the poly(1,4-phenylene) can provide different properties, depending on what the poly(1,4-phenylene) is substituted with. Thus, it would not have been obvious to have selected a substituted poly(1,4-phenylene) polymer including a plurality of benzoyl substituted 1,4 phenylene units. For at least these reasons, claim 5 is in condition for allowance, and withdrawal of the rejection is respectfully requested.

Applicants respectfully disagree with the rejection of claim 51. Claim 51 recites:

A medical device comprising a flexible elongate element, the flexible elongate element formed by the process comprising the steps of:
providing a first polymer comprising a thermoplastic rigid rod polymer;
providing a second polymer compatible with the first polymer;
co-extruding the first polymer with the second polymer; and
not cross-linking the first polymer while cross-linking the second polymer.

(Emphasis added).

In formulating the rejection, the Office Action states that “Rau et al disclose that the medical device, comprising a crosslinkable polymer, is known in the art (thermoset polyimide; column 1, line 43); Rau et al therefore disclose a second polymer which is crosslinked or is not crosslinked.” Applicants respectfully disagree with this assessment of the teachings of Rau.

Applicants agree that Rau discloses the use of thermoset polyimide. However, Rau's inventive contributions are directed to thermoplastic polyimide (“It is the primary purpose of this invention to apply thermoplastic polyimide to the art of balloon catheter construction.” See Rau, at column 2, lines 30-32.). Rau merely identifies thermoset polyimide in order to distinguish thermoplastic polyimide from thermoset polyimide as discussed briefly in the background section of the disclosure. In fact, regarding thermoset polyimide, Rau states:

One material of choice for such catheters has been thermoset polyimide, primarily because of its high strength and flexibility in small diameter with very thin walls. Being thermoset, the polyimide used heretofore has involved complicated manufacturing procedures due to the fact that it is insoluble and “intractable” i.e., not meltable.

Rau, at column 1, lines 33-38. Thus, Rau expressly states that thermoset polyimide is not meltable. Furthermore, regarding advantages of thermoplastic materials over thermoset polyimide Rau states:

[t]hermoplastic materials lend themselves to simpler manufacturing techniques, such as extrusion in forming shafts and blow molding in forming the balloons than do the aforementioned thermoset polyimide materials due to the fact that they are soluble and meltable.

Rau, at column 1, lines 61-65. Thus, in view of that disclosed in Rau, one skilled in the art would conclude that thermoset polyimide is not extrudable, thus could not meet the emphasized limitations of claim 51. Namely, the identified passage of Rau is insufficient for disclosing the limitations of claim 51 of “co-extruding the first polymer with the second polymer” and “not cross-linking the first polymer while cross-linking the second polymer.” At no point throughout the document does Rau suggest the inclusion of a thermoset polyimide in a disclosed embodiment. For at least these reasons, claim 51 is

believed patentable over the cited art. Withdrawal of the rejection is respectfully requested.

In formulating the rejection of claim 52, it was stated in the Office Action that noted limitations of claim 52 “is given little patentable weight as it is directed to process limitation rather than a structural limitation.” Office Action, December 29, 2006, at page 6. Although Applicants agree with the Examiner that apparatus claims must be structurally distinguishable from the prior art, Applicants respectfully note that the statement provided in the Office Action is in conflict with the guidelines provided in the Manual of Patent Examination Procedure. Section 2114 of the M.P.E.P. states, “[w]hile features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function.” M.P.E.P. §2114, citing *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Despite the guidelines of the M.P.E.P., the Examiner appears to give no patentable weight to the limitations recited in claim 52.

Claim 52 recites:

A medical device comprising a flexible elongate element, the flexible elongate element formed by the process comprising the steps of:
providing a first polymer comprising a thermoplastic rigid rod polymer;
providing a second polymer compatible with the first polymer;
co-extruding the first polymer with the second polymer; and
cross-linking both the first polymer and the second polymer.

(Emphasis added). Thus, the flexible elongate element of the medical device is formed of a cross-linked first polymer and a cross-linked second polymer, clearly structural limitations of the medical device. The morphology of a polymer which has been cross-linked is clearly dissimilar from that of a polymer which has not undergone cross-linking. The molecular structure of a polymer is clearly a structural attribute of the polymer. Thus, as evidenced in the Office Action, structural limitations of claim 52 have not been adequately addressed in formulating the rejection.

Applicants note the remarks presented above regarding the allowability of claim 51 are equally applicable to claim 52, and thus reference to the above remarks is duly

made. For at least these reasons claim 52 is believed patentable over the cited art. Withdrawal of the rejection is respectfully requested.

Claims 45-50 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al., U.S. Patent No. 6,024,722, in view of Huntjens, U.S. Patent No. 3,388,095, and further in view of Weissleder et al., U.S. Patent No. 5,514,379. Applicants respectfully traverse this rejection.

As asserted above, there is no motivation to combine the teachings of Huntjens with those of Rau. Furthermore, Weissleder fails to provide the requisite motivation to establish a *prima facie* case of obviousness. For at least this reason, claims 45-50 are believed to be in condition for allowance. Withdrawal of the rejection is respectfully requested.

Claims 43-44 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al., U.S. Patent No. 6,024,722, in view of Huntjens, U.S. Patent No. 3,388,095, and further in view of Lau et al., U.S. Patent No. 6,517,570. Applicants respectfully traverse this rejection.

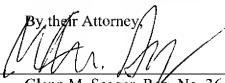
As asserted above, there is no motivation to combine the teachings of Huntjens with those of Rau. Furthermore, Lau fails to provide the requisite motivation to establish a *prima facie* case of obviousness. For at least this reason, claims 43-44 are believed to be in condition for allowance. Withdrawal of the rejection is respectfully requested.

Reexamination and reconsideration are respectfully requested. It is submitted that all pending claims are currently in condition for allowance. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at 612.677.9050.

Respectfully submitted,
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By their Attorney,

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